

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in April 2013.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-495

Trade Name: ENROFLOX 100
Pioneer: Baytril® 100
Ingredients: Enrofloxacin
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: February 28, 2013
Status: Rx
Route: Subcutaneous injection
Species: Beef, non-lactating dairy cattle, and swine
Drug Form: Injectable solution
Concentration: 100 mg/mL
Indications: **Cattle:** For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasturella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle (multiple-day therapy).
Swine: For the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*.

21 CFR 522.812

78 FR 19986-19987

ANADA Number: 200-509

Trade Name: Tilmovet® 90
Pioneer: Pulmotil® 90
Ingredients: Tilimicosin phosphate
Sponsor: Huvepharma AD
Approval Date: February 21, 2013
Status: VFD
Route: Oral, in feed
Species: Swine
Drug Form: Type A medicated article
Concentration: 90.7 g/lb
Indications: For the control of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

21 CFR 558.618

78 FR 19986-19987

ANADA Number: 200-531

Trade Name: Rumensin® plus Tylovet® 100
Pioneer: Tylan® 100 plus Rumensin®
Ingredients: Monensin USP plus tylosin phosphate
Sponsor: Huvepharma AD
Approval Date: February 1, 2013
Status: OTC
Route: Oral, in feed
Species: Cattle fed in confinement for slaughter
Drug Form: Type A medicated article
Concentration: Monensin USP – 80 g/lb
Tylosin phosphate – 40 and 100 g/lb
Indications: For improved feed efficiency, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses

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caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in cattle being fed in confinement for slaughter.

21 CFR 558.355

78 FR 19986-19987

ANADA Number: 200-532

Trade Name: MGA® plus Tylovet® 100
Pioneer: MGA® plus Tylan® 100
Ingredients: Melengestrol acetate plus tylosin phosphate
Sponsor: Huvepharma AD
Approval Date: March 7, 2013
Status: OTC
Route: Oral, in feed
Species: Heifers fed in confinement for slaughter
Drug Form: Type A medicated article
Concentration: Melengestrol acetate – 100 and 200 g/ lb (dry) and 500 g/lb (liquid)
Tylosin phosphate - 40 and 100 g/lb
Indications: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in heifers fed in confinement for slaughter.

21 CFR 558.342

78 FR 25182-25183

ANADA Number: 200-533

Trade Name: Deccox® plus Rumensin® plus Tylovet® 100
Pioneer: Deccox® plus Rumensin® plus Tylan® 100
Ingredients: Decoquinat plus monensin USP plus tylosin phosphate
Sponsor: Huvepharma AD
Approval Date: March 14, 2013
Status: OTC
Route: Oral, in feed
Species: Growing-finishing cattle being fed in confinement for slaughter
Drug Form: Type A medicated article
Concentration: Decoquinat – 27.2 g/lb
Monensin USP – 20, 30, 45, 60, 80, and 90.7 g/lb
Tylosin phosphate - 40 and 100 g/lb
Indications: For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, for improved feed efficiency, and for reduction in the incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes* in growing-finishing cattle being fed in confinement for slaughter.

21 CFR 558.195

78 FR 25182-25183

ANADA Number: 200-535

Trade Name: MGA® plus Bovatec® plus Tylovet® 100
Pioneer: MGA® plus Bovatec® plus Tylan® 100
Ingredients: Melengestrol acetate plus lasalocid sodium plus tylosin phosphate
Sponsor: Huvepharma AD
Approval Date: March 26, 2013
Status: OTC
Route: Oral, in feed
Species: Heifers fed in confinement for slaughter
Drug Form: Type A medicated article
Concentration: Melengestrol acetate – 200 and 500 g/lb
Lasalocid sodium – 68 and 91 g/lb
Tylosin phosphate - 40 and 100 g/lb

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Indications: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and reduced incidence of liver abscesses in heifers fed in confinement for slaughter.

21 CFR 558.342

78 FR 25182-25183

Sponsor Change

(A)NADA Numbers: 11-531, 11-674, 12-469, 31-512, 33-803, 35-918, 38-200, 39-483, 40-848, 43-606, 45-143, 47-278, 47-712, 48-010, 48-237, 48-271, 49-032, 55-097, 65-178, 65-461, 65-481, 65-486, 65-491, 65-496, 92-837, 93-516, 97-452, 98-569, 99-618, 108-963, 109-305, 117-689, 125-797, 126-236, 126-676, 127-627, 128-069, 132-028, 135-771, 136-212, 137-310, 138-869, 140-442, 200-023, 200-029, 200-165

Previous: Boehringer Ingelheim Vetmedica, Inc.

New Sponsor: Strategic Veterinary Pharmaceuticals, Inc.

Drug Labeler Code: 054628

21 CFR 510.600, 520.390a, 520.441, 520.443, 520.580, 520.600, 520.622a, 520.622b, 520.622c, 520.763a, 520.763b, 520.763c, 520.1408, 520.1660d, 520.1720a, 520.1900, 520.2220a, 520.2345d, 522.1044, 522.1222a, 522.1410, 522.1662a, 522.1680, 522.1720, 522.2220, 522.2424, 522.2483, 522.2662, 524.1580b, 524.1580c, 526.1696b, 529.1044a, 558.205
78 FR 21058-21060

Patent Corrections

NADA Number: 141-322

Patent number: 7,534,441

Original Expiration Date: May 9, 2026

Corrected Expiration Date: July 9, 2018